REMARKS

Claims 1-34 are pending in this application. Non-elected claims 1-2 and 7-34 have been cancelled without prejudice to or disclaimer of the underlying subject matter. Claims 3-6 have been amended to recite the elected sequence. Figure 2 has been amended to recite "Figure 2" and "Figure 2 continued" in the title for the Figure. Support for the amendments can be found throughout the specification, in the sequence listing, and in the claims as originally filed. Upon entry of these amendments, amended claims 3-6 will be pending. No new matter enters by way of these amendments.

1. Restriction/Election

Applicants acknowledge the finality of the restriction requirement but maintain their traversal. To facilitate prosecution, however, Applicants have removed the non-elected claims from the application.

Applicants acknowledge the finality of the election requirement to a single nucleotide sequence, but maintain their traversal. Applicants reiterate that election of a single nucleotide sequence is improper and Applicants believe no serious burden would result by the search and examination of all six of the nucleotide sequences in the claims. The election of a single nucleic acid sequence contravenes the USPTO policy as set forth in the Manual of Patent Examining Procedure stating that "to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided ... to permit a reasonable number of such nucleotide sequences to be claimed in a single application." (M.P.E.P., 8th ed., rev. 1, February 2003, Section 803.04). The MPEP further provides that "[i]t has been

determined that normally ten sequences constitute a reasonable number for examination purposes." (emphasis added) *Id.* While the Examiner requires that a single nucleotide sequence be selected, no reason has been provided for this deviation from articulated Patent Office policy.

Although Applicants disagree with the election requirement of a single nucleotide sequence, to facilitate prosecution the claims have been amended to reflect the elected SEQ ID NO: 2.

2. Objections to the Specification and Claims

The Examiner has objected to the specification because Applicants have allegedly "disclosed Figures 2A and 2B but the Brief Description of the Drawings only specifies Figure 2." Office Action at page 3. Applicants have amended the drawings to delete the reference to Figures 2A and 2B, and refer instead to "Figure 2," and "Figure 2 continued," respectively. As such, Applicants request this objection to the specification be withdrawn.

In addition, the Examiner has objected to claims 3-6 for allegedly "reading on non-elected inventions." Office Action at page 3. Applicants have amended the claims to reflect the nucleotide sequence elected in the Response to Restriction Requirement filed February 18, 2004. As such, Applicants request this objection to claims 3-6 be withdrawn as moot.

Applicants acknowledge and thank the Examiner for indicating that "[c]laim 6 is objected to but would be allowable if the claim was rewritten to over-come the

objections...." Office Action at page 11. Applicants assert that the objections to claim 6 have been overcome by the present amendments and claim 6 is now in condition for allowance.

3. Claim Rejections – 35 U.S.C. § 112, 1st Paragraph, Written Description

Claims 3-5 stand rejected under 35 U.S.C. § 112, first paragraph because the claimed subject matter allegedly was "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Office Action at pages 3-5. Applicants respectfully traverse this rejection.

The Examiner acknowledges that the Applicants have "isolated a cDNA clone from soybean, SEQ ID NO:1, that encodes SEQ ID NO:2...." *Id.* at page 4. However, the Examiner argues that Applicants have allegedly not described the claimed nucleic acid molecules. The basis for the Examiner's rejection is that the specification fails "to describe a representative number of polynucleotide sequences encoding SEQ ID NO: 2 falling within the scope of the claimed genus of polynucleotides, comprising sequences that encode polypeptides that are substantially identical to SEQ ID NO:2 or encode a protein with substantial identity to SEQ ID NO:2 or encode a polypeptide comprising SEQ ID NO:2 containing conservative amino acid substitutes." *Id.* at page 5. The Examiner further alleges that "Applicants do not identify essential regions of SEQ ID NO:2 encoded by SEQ ID NO:1...." Office Action at page 4. Apparently, the Examiner contends that "[s]ince the genus of proteins of SEQ ID NO:2 have not been described by specific structural features, the specification fails to provide an adequate written

description to support the breadth of the claims." *Id.* at page 6. Applicants respectfully traverse.

An adequate written description of a genus of nucleic acids, as recited in claims 3-5 may be achieved by either "a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus." *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997). The feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non-members. *Id.*

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe," in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989). A related, and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326

(C.C.P.A. 1981). Thus, in order for Applicants to describe each and every molecule encompassed by the claims, it is not required that every aspect of those nucleic acid molecules (*e.g.*, "essential regions") be disclosed. *In re Alton,* 76 F.3d 1168, 1175 (Fed. Cir. 1996) (if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing even if every nuance of the claims is not explicitly described in the specification).

It is well-settled law that each nucleic acid molecule within a claimed genus does not need to be described by its complete structure. The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). In contrast to the mere name "cDNA" provided in *Eli Lilly*, Applicants have provided a detailed chemical structure by way of the claimed nucleic acid molecule encoding SEQ ID NO: 2, as well as complements and specified variations thereof. Applicants have therefore satisfied the *Eli Lilly* test for written description.

Applicant's present disclosure not only provides the nucleic acid sequences required by the claims (*e.g.*, those encoding SEQ ID NO: 2), but further describes that the claimed nucleic acid molecules may include the recited sequence with additional sequences, for example, vectors comprising the claimed nucleic acid molecules (*see, e.g.*, specification at page 39, line 30 through page 42, line 20). The specification also describes, for example, nucleic acid molecules comprising single nucleotide polymorphisms (SNPs) and methods to identify sequences containing them (*see, e.g.*,

specification at page 28, lines 21-24), nucleic acid molecules encoding amino acid sequences having conservative substitutions (*see, e.g.,* specification at page 15, line 19 through page 16, line 12), fusion protein or peptide molecules or fragments thereof encoded by the nucleic acid molecules of the present invention (*see, e.g.,* specification at page 37, line 31 through page 38, line 2), plant and other homologue proteins and nucleic acid molecules (*see, e.g.,* specification at page 38, lines 3-13) and the disclosure of hybridization conditions (*see, e.g.,* specification at page 17, line 9 through page 18, line 7). Despite the numerous variations described for the claimed nucleic acid molecules in the present specification, the Examiner maintains that "Applicants fail to describe a representative number of polynucleotide sequences encoding SEQ ID NO: 2 falling within the scope of the claimed genus of polynucleotides, comprising sequences that encode polypeptides that are substantially identical to SEQ ID NO: 2 or encode a protein with substantial identity to SEQ ID NO:2 or encode a polypeptide comprising SEQ ID NO:2 containing conservative amino acid substitutions." Office Action at page 8.

The fundamental factual inquiry for satisfying the written description requirement is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, that applicants were in possession of the invention as now claimed. See, *e.g.*, *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997), M.P.E.P. § 2163.02. The Examiner has failed to provide reasons why a person skilled in the art at the time the application was filed would not have recognized that Applicants were in

possession of the invention as claimed in view of the disclosure of the application as filed.

The Examiner has offered no evidence to demonstrate, in light of Applicants' disclosure, why one of ordinary skill in the art would reasonably doubt that the invention encompassed by Applicants' has not been adequately described in the present disclosure. As such, the Examiner has not met the burden to impose a written description rejection.

Applicants have provided a detailed chemical structure, *e.g.*., nucleic acid sequences encoding the amino acid sequence of SEQ ID NO: 2. Nucleic acid molecules falling within the scope of claims 3-5 are readily identifiable – *e.g.* they comprise a nucleic acid molecule having the nucleic acid sequence which can encode an amino acid sequence that is substantially identical to a sequence of SEQ ID NO: 2. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed through the present specification. Thus, there is no deficiency in the written description support for the claimed invention. Therefore, claims 3-5 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of this rejection are respectfully requested.

4. Rejection Under 35 U.S.C. §112, 1st Paragraph: Enablement

Claims 3-5 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly "[t]he specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims." Office Action at page 6.

More particularly, the Examiner alleges that "the specification, while being enabling for isolated nucleic acid sequences encoding SEQ ID NO:2 and plant transformation therewith, does not reasonably provide enablement for nucleic acid sequences encoding a polypeptide having an amino acid sequence that is substantially identical to SEQ ID NO:2, and isolated nucleic acid molecule comprising a nucleotide sequence that hybridizes under stringent conditions to a nucleic acid sequence encoding SEQ ID NO:2 or an isolated nucleic acid sequence which encodes an amino acid sequence comprising SEQ ID NO:2 containing conservative amino acid substitutions and plant transformation therewith." *Id.* Applicants respectfully traverse this rejection.

The Examiner further alleges that "[t]he claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors." *Id.* The Examiner concludes that "given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled." *Id.* at page 10. Applicants respectfully disagree.

It is well established patent jurisprudence that Applicants need not teach "conventional and well-known genetic engineering techniques" (*see, e.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000)), which would include the use of the claimed sequence with other nucleic acid sequences, Applicants submit the Examiner has not met the required burden. Furthermore, Applicants submit that an analysis of the criteria presented by *In re Wands* supports Applicant's position that no undue experimentation would be required to make

and use the claimed invention. *See In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1998).

The first *Wands* criterion is the quantity of experimentation necessary. The "make-and-test" quantum of experimentation is reduced by the extensive knowledge, *e.g.*, of conservative nucleotide substitutions, identification of an active site, and radiometric synthase assay conditions, to which a person of ordinary skill in the art has access. Performing routine and well-known steps, such as sequence alignment protocols, molecular weight determination, and antibody hybridization assays, cannot create undue experimentation even if it is laborious. *See In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976).

The second and third *Wands* criteria relate to the amount of direction or guidance given, and the presence or absence of working examples. Again, the specification provides, for example, percent sequence identity, and discusses the use of the claimed SEQ ID NO to isolate additional sequences within a genome. *See, e.g.,* specification at page 14, line 26 through page 16, line 12, page 28, line 25 through page 31, line 28, page 47, line 25 through page 54, line 4 (Examples 1-5) and the sequence listing. Based on such disclosure, one of ordinary skill in the art would be enabled to make and use the invention commensurate in scope with the claims.

The fourth, fifth and sixth *Wands* criteria focuses on the nature of the invention, the state of the art and the relative skill in the art. The present invention relates to nucleic acid sequences, and the specification further describes amino acid sequences derived therefrom, antibodies, constructs and methods related thereto. *See, e.g.,* specification at page 13, line 3 through page 16, line 12 (describing polypeptide molecules and

homologues), and page 39, line 4 through page 47, line 17 (describing use of the claimed nucleic acid molecules in methods of transforming plants). Practitioners in this art are guided by considerable knowledge and resources on the conditions and approaches that can be utilized to identify, confirm and introduce into other hosts, nucleic acid and amino acid sequences.

The seventh criterion considers the predictability of the art. The Examiner has presented no evidence why one of ordinary skill in the art would not, for example, be able to predict conservative substitutions or use the nucleic acid molecules of the present invention in the disclosed uses. Applicant asserts that the specification discloses sufficient guidance to render these results predictable. *See, e.g.*, Specification at page 10, line 21 through page 16, line 12, and page 47, line 25 through page 85, line 22 (Examples 1-37).

The eighth criterion focuses on the breadth of the claims. Enablement is satisfied when the disclosure "adequately guide[s] the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility". *See In re Vaeck,* 947 F.2d 488, 496, 20 U.S.P.Q.2d 1438, 1445 (Fed. Cir. 1991). In the present case, one of skill in the art is specifically guided by the disclosure to look to, *e.g.*, sequence identity data in making that determination.

The Examiner has provided neither evidence supporting the rejection nor any explanation of why the specification allegedly fails to enable the nucleic acid molecules of claims 3-5. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (B.P.A.I. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement). Moreover, because

the above analysis illustrates that the specification clearly enables at least the methods of making and using the invention as set forth in the Examples, and the claims, the enablement requirement has been satisfied. *Cf. Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) ("the enablement requirement is met if the description enables any mode of making and using the invention") (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Furthermore, the analysis of the *Wands* factors, discussed *supra*, conclusively establishes that one of ordinary skill in the art would be able to make and use the claimed invention based on the disclosure in the specification. Accordingly, Applicants respectfully request reconsideration and withdrawal of the enablement rejection under 35 U.S.C. § 112, first paragraph.

5. Claim Rejections – 35 U.S.C. § 102(b)

Claims 3-5 stand rejected under 35 U.S.C. § 102(b) as allegedly "anticipated by Elliott et al. (1996, The Plant Cell 8:155-168)."

"It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986). Further, "an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device." *In re Donohue*, 766 F.2d 531, 226 U.S.P.Q. 619 (Fed. Cir. 1985). Applicants submit that Elliot does not anticipate the claims of the present invention.

The Examiner alleges that the cited reference teaches "a nucleic acid sequence that encodes the *Arabidopsis* AINTEGUMENTA (ANT) protein that exhibits 38%

identity to Applicants' SEQ ID NO: 2." Office Action at page 10. The Examiner goes on to conclude that "[g]iven that the encoded protein of Elliot et al is the *Arabidopsis* homologue to Applicants' polypeptide, the nucleic acid sequence of Elliot et al encodes a polypeptide that is substantially identical to SEQ ID NO:2, comprises conservative substitutions, and the isolated nucleic acid sequence of Elliot et al would hybridize under stringent conditions to Applicants' sequence and encode a polypeptide with substantial identity to SEQ ID NO:2, and as such, Elliot et al anticipate the claimed invention." Whatever else Elliott, *et al.* teaches, it does not disclose a nucleic acid molecule comprising a nucleotide sequence, or its complement, which can encode an amino acid sequence substantially similar to SEQ ID NO: 2 or containing conservative amino acid substitutions.

The Examiner has not shown that the amino acid sequence described in Elliot is substantially identity to SEQ ID NO: 2 or that comprises SEQ ID NO:2 containing conservative amino acid substitutions. The Examiner alleges that Elliot describes an amino acid sequence that exhibits 38% identity to Applicants' SEQ ID NO: 2. Applicants submit that the ANT protein of Elliot, *et al.* is not substantially similar to SEQ ID NO: 2. *See*, specification at page 15, lines 10 through 18. As such, whatever else Elliot describes, it does not describe a protein with substantial identity to SEQ ID NO:2.

Moreover, the Examiner provides no support for the conclusion that the sequence of Elliot *et al.* can hybridize under stringent conditions to a nucleic acid sequence encoding SEQ ID NO: 2. The Examiner appears to shift the burden of proof to Applicants to provide evidence that the nucleic acid sequence that encodes the *Arabidopsis* ANT

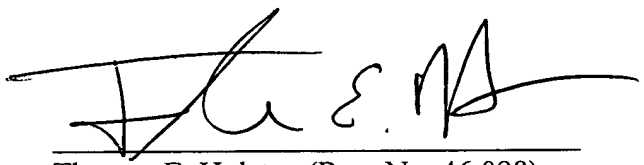
protein would not hybridize to a nucleic acid sequence that encodes SEQ ID NO: 2 under the claimed hybridization conditions. This is not the law.

Absent a teaching of each and every element of the claims, the reference cited by the Examiner does not anticipate claims 3-5 and the rejection should be reversed. Accordingly, for at least the foregoing reasons, the rejection of claims 3-5 under 35 U.S.C. § 102(b) is improper. Reconsideration and withdrawal of this rejection is respectfully requested.

Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,



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